

PSJ17 Exh 66

Prescription Drug Abuse & Alliance to Prevent the Abuse of Medicines

Background

Prescription drug abuse is a growing health concern in the United States and inappropriate use of opioid products is a significant part of the problem. The 2012 *National Survey on Drug Use and Health* conducted by the Substance Abuse and Mental Health Services Administration reported that “Among persons aged 12 or older in 2011-2012 who used pain relievers non-medically in the past 12 months, 54.0 percent got the drug they used most recently from a friend or relative for free, and 10.9 percent bought the drug from a friend or relative. An annual average of 4.3 percent got pain relievers from a drug dealer or other stranger, and 0.2 percent bought them on the Internet.”

Lawmakers and regulators have taken notice. In the U.S. Congress, there have been several hearings and numerous bills introduced to address various aspects of the issue, including the approval of abuse deterrent formulations, such as Teva’s AD Hydrocodone. Other bills would: restrict the number of prescriptions a physician could write for an individual patient; limit the prescribing of pain medication for severe-only pain and preclude it for moderate-to-severe pain; : limit the number of pharmacies from which a patient may get their pain medications. Additionally, the FDA has issued draft “abuse deterrence” guidance for industry, convened a two-day public meeting to get reaction from interested stakeholders, actively promoted responsible prescribing education programs for physicians and established an internal opioid task force. Most recently, the FDA has made label change requirements for opioids intended to limit prescribing as well as requiring product sponsors to conduct post market studies to gather more information about the risks of opioid abuse. The Drug Enforcement Agency has also publicly advocated for the rescheduling of hydrocodone products from Schedule III to the more restrictive Schedule II.

In the absence of better ideas, policymakers have offered a variety of legislative and regulatory initiatives that target the individual links in the supply chain that will, at best, have a minimal impact in truly addressing in a comprehensive manner the problem. Furthermore, this approach has resulted in a fear among physicians of intensified scrutiny by law enforcement and has caused many to stop or greatly reduce the number of prescriptions they write for “pain patients.” Pharmacies are also proactively questioning both physicians about their prescribing practices and patients on their need for these medicines. The bottom line is that legitimate access for those patients who truly need these medicines is being reduced.

Relevance to Teva

Recognizing that this hostile environment will hinder the ability of Teva to properly market our current pain products as well as our pipeline AD Hydrocodone product and the pain related NTE drugs that are being internally reviewed at this time, Teva conceived and worked behind the scenes to establish the “Alliance to Prevent the Abuse of Medicines” (Alliance). The Alliance is led by Teva, CVS-Caremark (the nation’s largest pharmacy health provider in the U.S.), Cardinal Health (the second largest wholesaler in the country), Prime Therapeutics (a leading, stand alone prescription benefit manager serving 20 million Americans) and the American Medical Association (the largest representative of the nation’s doctors).

The Alliance brings together representatives from across the domestic supply chain in the United States. The goal of the Alliance is to partner with policymakers to craft systemic, workable and effective solutions that target the misuse and diversion while preserving access. Policy solutions under consideration include: strengthening Prescription Drug Monitoring Programs; incentivizing physician and patient education initiatives, positioning the problem as a public health issue and not a law enforcement one; regulating pill mills; and improving patient focused drug take back programs.

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Next Steps

The Alliance is scheduled to go public this month. Next immediate steps include: additional member recruitment, determination of agreed upon policy alternatives, development of strategic programming/tactical calendar, and development of a full website.